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**1.4 Product information****1.4.3 Patient Information Leaflet (PIL)**

**READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START TAKING THIS MEDICINE BECAUSE IT CONTAINS**

**IMPORTANT INFORMATION FOR YOU.**

- KEEP THIS LEAFLET. YOU MAY NEED TO READ IT AGAIN.
- IF YOU HAVE ANY FURTHER QUESTIONS, ASK YOUR DOCTOR OR PHARMACIST.
- THIS MEDICINE HAS BEEN PRESCRIBED FOR YOU ONLY. DO NOT PASS IT ON TO OTHERS. IT MAY HARM THEM, EVEN IF THEIR SIGNS OF ILLNESS ARE THE SAME AS YOURS.
- IF YOU GET ANY SIDE EFFECTS, TALK TO YOUR DOCTOR OR PHARMACIST. THIS INCLUDES ANY POSSIBLE SIDE EFFECTS NOT LISTED IN THIS LEAFLET.

**What is in this leaflet**

1. What Balfen (Ibuprofen 200 mg Tablets) are and what they are used for
2. What you need to know before you take Balfen (Ibuprofen 200 mg Tablets)
3. How to take Balfen (Ibuprofen 200 mg Tablets)
4. Possible side effects.
5. How to store Balfen (Ibuprofen 200 mg Tablets)
6. Further Information.

**1. What Balfen (Ibuprofen 200 mg Tablets) are and what they are used for**

Ibuprofen contains the active substance ibuprofen. It belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs provide relief by changing the body's response to pain and high temperature.

Ibuprofen tablets are used for the symptomatic treatment of mild to moderate pain, such as headache, dental pain, period pain and fever and pain as the result of a cold

**2. What you need to know before you take Balfen (Ibuprofen 200 mg Tablets)****Do not take Balfen (Ibuprofen 200 mg Tablets):**

- If you are allergic to ibuprofen or any other ingredients of this medicine
- If you have had an allergic reaction such as asthma, difficulty in breathing, swelling of the face, tongue or throat nettle rash, itchy runny nose to acetylsalicylic acid (ASA) or other NSAIDs
- If you have (or have had two or more episodes of) a stomach ulcer or bleeding
- If you have had gastrointestinal perforation or bleeding when taking NSAIDs
- If you are suffering from cerebrovascular or other active bleeding
- If you are suffering from unclarified blood-formation disturbances
- If you have severe dehydration (caused by vomiting, diarrhoea or insufficient fluid intake)
- If you have severe liver, kidney or heart failure
- If you are in the last 3 months of pregnancy.



- Ibuprofen contraindicated in children under 6 years (less than 20 kg body weight).

**Warnings and precautions:**

Talk to your doctor or pharmacist before taking Ibuprofen:

- if you have recently had major surgery
- if you have or have had asthma or allergic disease as shortness of breath may occur
- if you suffer from hayfever, nasal polyps or chronic obstructive respiratory disorders as an increased risk of allergic reactions exists. The allergic reactions may present as asthma attacks (so-called analgesic asthma), Quincke's oedema or urticaria
- if you have heart problems
- if you have a history of gastrointestinal disease (such as ulcerative colitis, Crohn's disease)
- if you have systemic lupus erythematosus or mixed connective tissue disease (a disease affecting the skin, joints and kidneys)
- if you have certain hereditary blood formation disorders (e.g. acute intermittent porphyria)
- if you have a blood clotting disorder
- if you are taking other NSAIDs. The use with concomitant NSAIDs, including cyclo-oxygenase-2 specific inhibitors, increases the risk of adverse reactions (see section "Other medicines and Ibuprofen" below) and should be avoided
- if you have chicken pox (varicella) it is advisable to avoid use of Ibuprofen
- if you are elderly

Patients with kidney or liver problems should first consult a doctor before taking ibuprofen tablets. Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.

You should discuss your treatment with your doctor or pharmacist before taking ibuprofen if you:

- have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack, 'TIA')
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

Very rare reports of potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of ibuprofen. Patients are at higher risk of such reactions during the first month of therapy. Stop taking Ibuprofen and talk to your doctor or pharmacist if you notice a skin rash, mucosal lesions, or any other signs of allergic reactions.

Undesirable effects may be minimised by using the minimum effective dose for the shortest period of time. The elderly are at increased risk of side effects.

In general the habitual use of (several sorts of) analgesics can lead to lasting severe kidney problems. This risk may be increased under physical strain associated with loss of salt and dehydration. Therefore it should be avoided. There is a risk of renal impairment in dehydrated children and adolescents.



Prolonged use of any type of painkiller for headaches can make them worse. If this situation is experienced or suspected, medical advice should be obtained and treatment should be discontinued. The diagnosis of medication overuse headache (MOH) should be suspected in patients who have frequent or daily headaches despite (or because of) the regular use of headache medications.

NSAIDs may mask symptoms of infection and fever. In prolonged administration of Ibuprofen regular checking of your liver values, the kidney function, as well as the blood count, is required. Your doctor may ask you to have blood tests during treatment.

### **Other medicines and Balfen (Ibuprofen 200 mg Tablets)**

What should you avoid when you are taking this medicine?

Ibuprofen may affect or be affected by some other medicines. For example:

- Medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- Medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, angiotensin-II receptor antagonists such as losartan)

Some other medicines may also affect or be affected by treatment with ibuprofen. You should therefore always seek the advice of your doctor or pharmacist before you use ibuprofen with other medicines.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell them if you are taking:

- Acetylsalicylic acid, or other NSAIDs (anti-inflammatories and analgesics) - Since this may increase the risk of gastrointestinal ulcers or bleeding
- Digoxin (for heart insufficiency) - Since the effect of digoxin may be enhanced
- Glucocorticoids (medicinal products containing cortisone or cortisone-like substances) - Since this may increase the risk of gastrointestinal ulcers or bleeding
- Anti-platelet agents - Since this may increase the risk of bleeding
- Acetylsalicylic acid (low dose) - Since the blood-thinning effect may be impaired
- Medicines for thinning the blood (such as warfarin) - Since ibuprofen may enhance the effects of these medicines
- Phenytoin (for epilepsy) - Since the effect of phenytoin may be enhanced
- Selective serotonin reuptake inhibitors (medicines used for depression) - As these may increase the risk of gastrointestinal bleeding
- Lithium (a medicine for manic depressive illness and depression) - Since the effect of lithium may be enhanced
- Probenecid and Sulfinpyrazones (medicines for treating gout) - Since the excretion of ibuprofen may be delayed
- Medicines for high blood pressure and water tablets - Since ibuprofen may diminish the effects of these medicines and there could be a possible increased risk for the kidney
- Potassium sparing diuretics - Since this may lead to hyperkalaemia (high potassium levels in the blood)
- Methotrexate (a medicine for cancer or rheumatism) - Since the effect of methotrexate may be enhanced
- Tacrolimus and cyclosporin (immunosuppressive medicines) - Since kidney damage may occur
- Zidovudine (a medicine for treating HIV/AIDS) - Since the use of ibuprofen may result in



an increased risk of bleeding into a joint or a bleed that leads to swelling in HIV (+) haemophiliacs

- Sulfonylureas (antidiabetic medicines) - Interactions may be possible
- Quinolone antibiotics - Since the risk for convulsions may be increased
- Mifepristone (medicine prescribed for pregnancy termination) - Since ibuprofen may reduce the effect of this medicine
- Bisphosphonates (medicines prescribed to treat osteoporosis) - Since these may increase the risk of gastrointestinal ulcers or bleeding
- Oxpentifylline (pentoxifylline) (medicine prescribed to increase the blood flow to arms and legs) - Since this may increase the risk of gastrointestinal bleeding
- Baclofen, a muscle relaxant - Since the toxicity of baclofen may be enhanced

### **Low dose ASA**

Do not take this medicine if you are taking ASA at doses of above 75 mg daily. If you are on low-dose ASA (up to 75 mg daily) speak to your doctor or pharmacist before you take Ibuprofen.

**Ibuprofen with alcohol** Consumption of alcohol should be avoided while taking Ibuprofen as it may intensify possible side effects.

### **Pregnancy and breast-feeding**

Do not take Ibuprofen in the last 3 months of pregnancy. If you are in the first 6 months of pregnancy, breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Ibuprofen tablets belong to a group of medicines which may impair fertility in woman. This effect is reversible on stopping the medicine. It is unlikely that Ibuprofen, used occasionally, will affect your chances of becoming pregnant, however tell your doctor before taking this medicine if you have problems becoming pregnant.

### **Driving and using machines**

For short-term use and at normal dosage this medicine has no or negligible influence on the ability to drive and use machines. If side-effects such as tiredness, dizziness, drowsiness and visual disturbances occur, do not drive or operate machines. Alcohol consumption increases the risk of these side effects.

### **3. How to take Balfen (Ibuprofen 200 mg Tablets)**

**Always take Balfen (Ibuprofen 200 mg Tablets) exactly as your doctor has told you.**

**Check with your doctor or pharmacist if you are not sure.**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The product is intended for short term use only. You should take the lowest effective dose for the shortest time necessary to relieve your symptoms.

You should not take Ibuprofen for longer than 3 days in the case of migraine or fever, or 4 days for the treatment of pain unless your doctor tells you to. If symptoms persist or worsen consult your doctor:

Adults and adolescents over 40 kg body weight(12 years of age and above):



The recommended dose is 200 mg to 400 mg (1 or 2 tablets), up to three times a day as required. Leave at least four hours between 200 mg (1 tablet) doses and at least six hours between 400 mg (2 tablets) doses. Do not take more than 1200 mg (6 tablets) in 24 hours. For treatment of migraine headache the recommended dose is 2 tablets of 200 mg as a single dose. If necessary, take 400 mg (2 tablets) dose with intervals of 4 to 6 hours. Do not take more than 1200 mg (6 tablets) in any 24 hours.

Use in children over 6 years (20 kg – 40 kg body weight): The recommended daily dose is 20 mg to 30 mg of ibuprofen per kg body weight divided into three or four separate doses as shown in the table below. Leave at least six to eight hours between doses.

Body weight	Single dose	Maximum daily dose
20 kg – 29 kg	one 200 mg tablet (equals 200 mg ibuprofen)	three 200 mg tablets (equals 600 mg ibuprofen)
30 kg – 39 kg	one 200 mg tablet (equals 200 mg ibuprofen)	four 200 mg tablets (equals 800 mg ibuprofen)

If in children aged from 6 years and in adolescents this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

Use in children under 6 years (less than 20 kg body weight): Ibuprofen is contraindicated for use in children under 6 years (less than 20 kg body weight).

**Method of administration** Ibuprofen tablets are swallowed whole with plenty of water. Do not chew the tablets. Patients with a sensitive stomach should take the tablets during a meal. Taking the tablets after a meal may delay the onset of pain or fever relief. Do not exceed the recommended dose or take more frequently than recommended.

#### If you take more Ibuprofen than you should

You may experience nausea, stomach ache, headache, vomiting, diarrhoea, ringing in the ears, vomiting blood and blood in stools. More serious poisoning can lead to dizziness, drowsiness, excitation, disorientation, low blood pressure, reduced breathing (respiratory depression), blue discolouring of the skin and mucosa (cyanosis), loss of consciousness, convulsions and coma. You should seek immediate medical advice in the event of an overdose, even if you feel well.

#### If you forget to take Ibuprofen

Simply refer to the directions above on how to take the medicine and do not take more than is advised.

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. Side effects may be minimized by taking the lowest dose for the shortest time necessary to relieve the symptoms. Elderly people using this product are at increased risk of developing problems associated with side effects. Medicines such as Ibuprofen may be associated with a small increased risk of heart attack (“myocardial infarction”) or stroke. Some of the undermentioned undesirable effects are less frequent when the maximum daily dose is 1200 mg compared to high-dose therapy in rheumatism patients



**If you think you have any of the following side effects or symptoms, stop taking this medicine and seek immediate help:**

- Stomach and intestinal ulcers, sometimes with bleeding and perforation, vomiting blood or have black tar-like stools (common: may affect up to 1 in 10 people)
- kidney disease with blood in the urine which can be associated with renal failure (uncommon: may affect up to 1 in 100 people)
- severe allergic reactions (very rare: may affect up to 1 in 10,000 people) such as:
  - difficulties in breathing or unexplained wheezing
  - dizziness or faster heartbeat
  - drop in blood pressure leading to shock
  - swelling of your face, tongue or throat
- Potentially life-threatening skin rashes with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Steven-Johnson syndrome) or serious skin reactions which starts with painful red areas, then large blisters and ends with peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell (toxic epidermal necrolysis) (very rare: may affect up to 1 in 10,000 people)
- severe condition of the skin that may affect the mouth and other parts of the body with symptoms including: red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body. The spots may blister or may progress to form raised, red, pale-centred marks. Those affected may have fever, sore throat, headache and/or diarrhoea (very rare: may affect up to 1 in 10,000 people)
- severe flaking or peeling of the skin (very rare: may affect up to 1 in 10,000 people)
- inflammation of the pancreas with severe upper stomach pain, often with nausea and vomiting (very rare: may affect up to 1 in 10,000 people)
- nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine which may be signs of hepatitis or liver failure (very rare: may affect up to 1 in 10,000 people)
- disease of the heart with shortness of breath and swelling of the feet or legs due to fluid build-up (heart failure) (very rare: may affect up to 1 in 10,000 people)
- aseptic meningitis (infection around the brain or spinal cord with symptoms including fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light and clouding of the mental state and thus not being fully in contact with the environment) (very rare: may affect up to 1 in 10,000 people)
- heart attack (“myocardial infarction”, very rare: may affect up to 1 in 10,000 people) or stroke (not known: frequency cannot be estimated from the available data)
- severe kidney damage (papillary necrosis), particularly in long term use (rare: may affect up to 1 in 1,000 people)
- worsening of infection-related inflammations (e.g. development of flesh eating bacteria syndrom) particularly if using other NSAIDs (very rare: may affect up to 1 in 10,000 people)

Stop taking the medicine and tell your doctor if you experience:

Very common (may affect more than 1 in 10 people)

- Indigestion or heartburn
- Abdominal pain (pains in your stomach) or other abnormal stomach Uncommon (may affect up to 1 in 100 people):



- Visual disturbances

Tell your doctor if you experience any of the below side effects:

Very common (may affect more than 1 in 10 people)

- Nausea, wind, diarrhoea, constipation, vomiting

Common (may affect up to 1 in 10 people):

- headache, sleepiness, dizziness, spinning sensation tiredness, agitation, inability to sleep, irritability
- stomach and intestinal ulcers, sometimes with bleeding and perforation; hidden blood loss which may lead to a condition in which there is a decreased number of red blood cells (symptoms include tiredness, headaches, being short of breath when exercising, dizziness and looking pale), black tar-like stools, vomiting blood, mouth ulcers and cold sores, inflammation of the colon (symptoms include diarrhoea, usually with blood and mucus, stomach pain, fever), worsening of inflammatory bowel disease, inflammation of bowel wall.

Uncommon (may affect up to 1 in 100 people):

- Hives, itching, unusual bleeding or bruising under the skin, skin rash, asthma attacks (sometimes with hypotension)
- Runny or blocked nose, sneezing, facial pressure or pain, difficulty in breathing
- Inflammation of the stomach (symptoms include pain, nausea, vomiting, vomiting blood, blood in the bowel motions)
- Increased sensitivity of the skin to sun
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, sometime with high blood pressure
- Fluid build-up in the body's tissues especially in patients with high blood pressure or kidney problems

Rare (may affect up to 1 in 1,000 people)

- A disease affecting the skin, joints and kidneys (lupus erythematosus syndrome)
- Depression, confusion, hallucinations, mental illness with strange or disturbing thoughts or moods
- Buzzing, hissing, whistling, ringing or other persistent noise in the ears
- Increase of blood urea nitrogen, serum transaminases and alkaline phosphatase, decrease in haemoglobin and haematocrit values, inhibition of platelet aggregation, prolonged bleeding time, decrease of serum calcium, increase in serum uric acid, all seen on a blood test
- Loss of vision

Very rare (may affect up to 1 in 10,000 people):

- fast or irregular heart beats (palpitations)
- fluid build-up in the body's tissues
- high blood pressure
- inflammation of the food pipe, narrowing of intestines
- liver disease, liver damage (especially in long-term use), liver failure, yellowing of the skin and/or eyes, also called jaundice



- unusual hair loss or thinning
- severe skin infections with soft tissue complications may occur if you have chicken pox
- menstrual period disorders
- build-up of fluid in the lungs, symptoms include breathlessness, which may be very severe and usually worsens on lying down

Not known (frequency cannot be estimated from available data)

- worsening of an inflammatory disease that can affect any part of the gastrointestinal tract (symptoms include pain, fever, diarrhoea and loss of weight), worsening of inflammation of the colon ( symptoms diarrhoea, usually with blood and mucus, stomach pain, fever)

Reporting of side effects If you get any side effects,talk to your doctor or pharmacist.

### **5. How to store Balfen (Ibuprofen 200 mg Tablets)**

- Store below 30°C.
- Pack size : 10x10 Alu-PVC blister  
1000's HDPE container

### **6. Further information**

#### **What Balfen (Ibuprofen 200 mg Tablets) contain:**

- Each film coated tablet contains :

Ibuprofen BP ....200 mg

The other ingredients are:

Colloidal Silicon Dioxide	USP/NF
Microcrystalline Cellulose	BP
Maize Starch (dry mix)	BP
Maize Starch (binder)	BP
Purified water	BP
Purified Talc	BP
Magnesium Stearate	BP
Microcrystalline Cellulose	BP
Colloidal Silicon Dioxide	USP/NF
Maize Starch	BP
Hypromellose (15 CPS)	BP
Isopropyl Alcohol	BP
Dichloromethane	BP
Polysorbate -80	BP
Titanium Dioxide	BP
Purified Talc	BP
Colour Lake of Erythrosine	IHS





**What Balfen (Ibuprofen 200 mg Tablets) look like and the contents of the pack:**

- Balfen (Ibuprofen 200 mg Tablets) are Pink coloured circular biconvex film coated tablets.

**The marketing authorisation holder and manufacturer**

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